

REMARKS

With this Response, claims 1-16 are pending in the present application. Claims 6, 7 and 16 have been withdrawn from consideration. Claims 17-24 have been added.

Claim rejections under 35 U.S.C. § 102(e)

The Examiner rejected claims 1-5 and 8-15 under 35 U.S.C. § 102(e) as being anticipated by Lappe et al. (6,514,461) or, alternatively, Anderson et al. (6,394,954). Applicant respectfully disagrees with this rejection.

The Lappe et al. reference does not anticipate claims 1, 8 and 15.

In general, Lappe et al. disclose a system for automatically testing a fluid specimen. The disclosed system utilizes an assaying device (30) comprising an integrated aliquot delivery mechanism actuatable to wet a test strip (115) with an aliquot delivered from the fluid specimen. The assaying device (30) is configured to operate in conjunction with an electronic reader device (28) capable of actuating the aliquot delivery mechanism and reading the reaction of the test strip (115). The reader device (30) defines a keyed receptacle (70) for accommodating a complementary shaped cup housing in a particular orientation.

With regards to the assaying device (30), Lappe et al. discloses that it comprises a collection cup (32) and a cap (34) which carries one or more test strips (115). The test strips (115) are positioned in compartments (131) of the cap, and a cap top surface (96) covers the test strips (115). Transparent windows (114A, 114B, 114C) defined in the cap top surface (96) enable the test strips (115) to be visible through the cap top surface (96). Col. 6: 38-41.

In the Office Action, the Examiner alleges that the windows (114A, 114B, 114C) disclosed in Lappe et al. read on the windows of the presently pending claims. However, nowhere in Lappe et al. are the windows of independent claims 1, 8 or 15 disclosed or suggested. *See, e.g.*, claim 1 (“at least one window has a shape corresponding to the shape of at least one test device so as to maintain the at least one test device in a fixed location during scanning”); claim 8 (“at least one window has a

shape corresponding to the shape of the test device so as to securely maintain the test device in a fixed position during scanning”); claim 15 (“wherein the at least one window has a shape corresponding to the shape of the test device so as to securely maintain the test device in a fixed position during scanning”). Instead, as cited by the Examiner, Lappe et al. disclose that the windows (114A, 114B, 114C) “cover[] the test strip....” (see col. 6:38-46 (emphasis added)) and enable the test strips (115) to be visible through the cap top surface (col. 6: 38-41). Moreover, as best seen in Figure 4, these windows (114A, 114B, 114C) do not have the same shape as the test strips (115), as the windows (114A, 114B, 114C) cover only portions of the test strips (115). Thus, nowhere is it disclosed or suggested in Lappe et al. that the windows (114A, 114B, 114C) have a shape corresponding to the test strips (115) so as to maintain the position of the test strips (115) in a fixed position during scanning.

Indeed, even if the Examiner were to read the compartments (131) on the windows of claims 1, 8 or 15, Lappe et al. provides virtually no disclosure on the shape of the compartments (131). For example, Figure 7 is the only figure referencing a compartment (131); however, reference numeral 131 appears to be pointing to an interior sidewall of the cap (34) and, therefore, does not provide any disclosure of the shape of the compartments (131). As such, the compartments (131) likewise cannot be permissibly read on the windows of claims 1, 8 or 15.

In addition, in the Office Action, the Examiner read the recess (70) disclosed in Lappe et al. on the template recited in independent claims 1, 8 and 15. However, the recess (70) disclosed in Lappe et al. is quite different from the claimed templates. For example, nowhere in Lappe et al. is it disclosed or suggested that the recess (70) is “configured to fit on a scanning surface of [a] scanner,” as required in claim 1; “plac[ed] on a scanning surface of a scanner,” as required in claim 8; or “scan[ed]... on a scanning surface of a scanner so as to generate a digital image” thereof, as required in claim 15. Instead, the recess (70) merely accommodates a bottom portion of the collection cup (32).

In view of the above, Applicant submits independent claims 1, 8 and 15, and dependant claims 2-5, 9-14 that depend upon claims 1 and 8, respectively, are not anticipated by Lappe et al.

The Anderson et al. reference does not anticipate claims 1, 8 and 15.

Anderson et al. disclose an immunoassay device (200) that includes a housing (202) generally surrounding a test strip (100). Col 36: 41-42. As seen in Figure 2, the housing (202) includes a test window (214) through which a test result of an immunoassay is viewed. To be analyzed, the immunoassay device (200) is inserted into a cassette slot of a reader device (600). For example, as shown in Figure 9, when the immunoassay device (202) is inserted into the reader device (600), an actuator wheel (902) and an actuator spring (not shown) work together to bring reader head (706) down to within about 0.010 inches of the immunoassay test strip (100) within the housing (202) of the immunoassay device (200). The reader head (706) is then stepped across the test window (214) to read the test strip (100). *See* col. 19: 32-49.

In the Office Action, the Examiner read the test window (214) on the windows claimed in the present application. However, nowhere in Anderson et al. are the windows of independent claims 1, 8 or 15 disclosed or suggested. *See, e.g.*, claim 1 (“at least one window has a shape corresponding to the shape of at least one test device so as to maintain the at least one test device in a fixed location during scanning”); claim 8 (“at least one window has a shape corresponding to the shape of the test device so as to securely maintain the test device in a fixed position during scanning”); claim 15 (“wherein the at least one window has a shape corresponding to the shape of the test device so as to securely maintain the test device in a fixed position during scanning”). Instead, the test window (214) merely permits the test strip (100) to be viewed as a reader head (706) scans the device (200). *See* col. 18: 1-15. Moreover, as shown in Figure 2A and Figure 3, the test window (214) only partially covers the test strip (100). Thus, nowhere is it disclosed or suggested in Anderson et al. that the window (214) has a shape corresponding to the test strip (100) so as to maintain the position of the test strip (100) in a fixed position during scanning.

Indeed, Anderson et al. discloses very little as to how the test strip (100) is held in place in the housing (202). For example, Anderson et al. does not appear to disclose whether or not the test strip (100) is maintained in a fixed position in the housing (202) during scanning or, instead, if the test strip (100) has freedom to move around in the housing (202) during scanning.

Accordingly, Applicant submits independent claims 1, 8 and 15, and dependant claims 2-5, 9-14 that depend upon claims 1 and 8, respectively, are not anticipated by Anderson et al.

New Claims

Claims 17-24 have been added. New claims 16-20 depend upon independent claim 1, new claims 21 and 22 depend upon independent claim 8, and new claims 23 and 24 depend upon independent claim 15. Because independent claims 1, 8 and 15 are believed to be allowable, as indicated above, new claims 17-24, which recite additional unique features, are likewise believed to be allowable.


Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **532812000200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By 
Kaare D. Larson
Registration No.: 51,920
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-5163